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09/322,067	05/27/99	SKOLNICK	J 10886/047001

020985
FISH & RICHARDSON, PC
4350 LA JOLLA VILLAGE DRIVE
SUITE 500
SAN DIEGO CA 92122

HM12/1009

EXAMINER

BORIN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

10/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/322,067

Applicant(s)

Skolnick et al

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 16, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-14, 16-20, 22, and 44-60 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-14, 16-20, 22, and 44-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s): _____
- 18) Interview Summary (PTO-413) Paper No(s): _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

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DETAILED ACTION

Status of Claims

1. Amendment filed 07/16/01 is acknowledged. Claims 1,15,21,23-43 are canceled. Claims 2-14,16-20,44-52 are amended. Claims 53-60 are added. Claims 2-14, 16-20,22, 44-60 are pending..

Sequence Listing

2. The Sequence Listing was approved by STIC for matters of form.

Specification

3. The disclosure is repeatedly objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, pages 4,5,8,46,83,97,100,101,122-124,126,128,136,137,141. Applicant is requested to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112, second paragraph.

4. Claims 2-14, 16-20,22, 44-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

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- A. Claim 53: The term "first amino acid" appears twice, in item (a) and then in item (b)(I). It is not clear whether it is the same or different residues.
- B. Claim 53, item (b)(iii). The term "third ... residue of the protein" (emphasis added) lacks antecedent basis as the previous two residues are defined as residues of the functional site, not protein in general.
- C. Claims 15,44 lack antecedent basis as their respective base claims are now canceled.

Claim Rejections - 35 USC § 101

5. Claims 15-22 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The rejection is maintained for reasons set forth in paragraph #4 of previous Office action.

Claims 1-22 are drawn to a "functional site descriptor" and libraries of said descriptors. The product as claimed is not a process, machine, manufacture, or composition of matter. "Functional descriptive material" consisting of data structures is nonstatutory when claimed as descriptive material per se. MPEP 2106, section "1. Nonstatutory subject matter".

6. Claims 53, 2-14,57 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to "a computer program product".

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The issue of patentability of computer programs is addressed in MPEP, section 2106.B.(a). In particular MPEP guides:

Data structures not claimed as embodied in computer-readable media are descriptive material *per se* and are not statutory because they are not capable of causing functional change in the computer.

Since a computer program is merely a set of instructions capable of being executed by a computer, the computer program itself is not a process and Office personnel should treat a claim for a computer program, without the computer-readable medium needed to realize the computer program's functionality, as nonstatutory functional descriptive material. When a computer program is recited in conjunction with a physical structure, such as a computer memory, Office personnel should treat the claim as a product claim.

In the instant case, the claims are drawn merely to a computer program product. Note that, in contrast, claims 8 of US 6,242,180, cited by applicant is drawn to a computer program product comprising a computer-readable medium.

Claim Rejections - 35 USC § 102 and 103.

7. Claim 2-14, 16-20, 22, 44-60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallace et al.

The claims as amended are drawn to a computer program product (and computer system containing said product) comprising description of one amino acid and geometric constraints between at least three different atoms located at three different residues. The "geometric constraints" are defined in the specification (p. 19) as relative coordinates, or distances, or angles.

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Wallace teaches method of searching protein structural databases for functional sites. In particular, the reference explores 3D coordinate templates for sites comprising a Ser-His-Asp triad.

The method of Wallace identifies an amino acid residue (i.e., as step (a) of claim 53) and relative positions between atoms of three residues, Ser, His, and Asp. The residues are considered to be interacting when the distance between the atoms of the three residues (i.e., the same as "geometric constraints" in step (b) of claim 53) is less than van der Waals radius plus 1Å. The distance can be measured between any atoms of the residues; however, the method works the best when the distance between Asp and Ser is defined by the distance between their functional oxygens. See p. 1004, left column. The flow diagram of method of implementing calculations of 3D template is given on Fig. 1. Further the method is applicable to, using applicant's terminology, "functional site descriptors" comprising not only the catalytic Ser-His-Asp triad but also atoms of different amino acid residues. See section "The catalytic tetrad" on pages 1007-1009.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference cited above. It is noted that the Wallace reference, although using a computer database Protein Data Bank, does not specifically mention usage of a computer to implement the described method of searching structural databases. It is Examiner's position that the amount of data analyzed is such that it necessitates the use of a computer; therefore the method used in Wallace is regarded as a computer implemented method, and its result - as a computer program product.

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However, should it appear unobvious that Wallace et al use a computer, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to implement method of Wallace using a computer to facilitate computation of huge amount of data.

In regard to claims 20-22 drawn to a library containing functional site descriptors, the generated output from database searches are always placed in a separate output file.

Response to argument

Applicant's argument is based on assertion that "nothing in Wallace suggests that a functional site descriptor can be represented by non-catalytic backbone atoms". However, the instant claims are not drawn to "catalytic" or "non-catalytic" atoms; all the claims require is that atoms belong to different residues. Further, applicants argue that Wallace does not suggest that a functional site descriptor incorporates one or more non-functional backbone atoms. The reference does suggest that (See section "The catalytic tetrad" on pages 1007-1009) and further, incorporation of one or more non-functional backbone atoms is not a limitation of the instant claims.

8. Claims 2-14, 16-20,22, 44-60 are rejected under 35 U.S.C. 102(b) as anticipated by Holm et al. The rejection is maintained for the reasons of record set forth for claims 1,3-10,12,15-22,43-50.

Response to arguments

Applicant argues that "Holm does not identify a subset of geometric constraints that represent only an active site or other functional site of these proteins". However, the focus of the reference is

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on the definition and prediction of the functional site descriptors, for example, the amino acid residues present in an enzymatic active site, such as in urease.

Conclusion.

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael

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Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 2, 2001

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read "Michael Borin", is written over the printed name and title.